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# Volunteer Information and Consent Form

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| Study Sponsor: | Philip Morris USA Inc. |
| Contract Research Organization | Covance Clinical Research Unit Inc.<br>Madison, WI |
| Study Doctor: | |
| Study Title: | A Multi-Center Study to Determine the Exposure to Cigarette Smoke of Adult U.S. Smokers who Spontaneously Switched to Lower or Higher FTC Tar Delivery of Cigarettes |
| Study No.: | PM Project TESMCFS/01/04 |

## Invitation

You are invited to take part in a research study at _____. About six months ago, as a follow-up to your participation in the Covance Smoking Study, you indicated in a telephone questionnaire that you switched your cigarette brand from the brand you smoked when you participated in the Covance Smoking Study about 18 months ago. During the telephone questionnaire you also indicated that you would be interested in participating in a follow-up study to the Covance Smoking Study. Only smokers who participated in the Covance Smoking Study and who have switched the brand of cigarettes they smoke since that study are eligible to participate in this study. This study will collect information about your recent smoking history, as well as samples of your blood and urine. This study is also being conducted at other research sites around the country.

## The Purpose of This Study

We are doing this study to see if there are changes in certain substances found in body fluids, such as blood and urine, in the smokers who participated in the Covance Smoking Study and who have switched their brand of cigarettes since that time. We are also trying to learn about any changes in smoking history in adult smokers who switch their brand of cigarettes.

Covance Clinical Research Unit Inc. is paid to conduct research. The study doctors in this study are being compensated by Covance Clinical Research Unit Inc. for the services they provide, but do not have a financial interest in the outcome of this study.

## Who Can Be in This Study?

Participants in this study must meet certain requirements. The study staff will ask you questions about your current and past health, what kinds of medicines you take, and what kinds of operations or diseases you may have had or have.

About 300 adult smokers (21 years of age or older) will participate in this study nationwide.

To be in this study, you must be 21 years of age or older. Females may not be pregnant or nursing. You may choose to quit smoking at any time. This study does not, however, offer smoking cessation treatment for people who decide to quit smoking, or any other health benefits. Use of certain products or medications may or may not be allowed in this study.

Please read the following chart carefully.

| MAY I HAVE...? | YES | NO | FOR HOW LONG? |
|---|---|---|---|
| • Any tobacco product other than manufactured cigarettes (e.g., pipe, cigar, snuff, chewing tobacco, bidis, or roll-your-own cigarettes) | | X | 3 months before, and during the study |
| • Nicotine-containing products (e.g., nicotine patch, nicotine spray, nicotine inhaler, nicotine gum, nicotine lozenge, nicotine pill or, nicotine-containing water) | | X | 3 months before, and during the study |
| • Caffeine-containing Products | X | | No restrictions to usual amount |
| • Alcohol-containing Products | X | | No restrictions to usual amount |
| • Prescription Medicines | X | | No restrictions to usual amount |
| • Over-the-Counter Medicines (e.g., non-prescription, including herbal products) | X | | No restrictions to usual amount |
| • Donate(d) or receive(d) blood products | | X | 3 months before, and during the study |
| • Participate(d) in a research study unless approved by the study doctor | | X | 3 months before, and during the study |

Formerly

## What Will Happen in This Study?

Before you can participate in this study, you must read and sign this consent form. If you qualify to be in the study, your participation will last over a period of up to 3 days. In this study you will:

- Come to the research unit twice within three days for an outpatient visit. Each outpatient visit may last up to three hours.

***IN THIS STUDY, YOU WILL:***

- Have your weight and height recorded-*once*
- Review your medical history, your smoking history, and what medicines you take–*twice*

- Fast (no food or drink except water) for 6 hours-*once*
- Have your blood drawn for laboratory tests-*once*
- Collect ALL your urine over a 24-hour period and bring in to the research unit -*once*
- Have urine tested for pregnancy (females only)-*once*
- Complete a questionnaire-*once*
- Use a smoking topography device with 4 cigarettes and bring in to the research unit-*once*

***OTHER PROCEDURES AND RESTRICTIONS***

Laboratory Test Results

If you have a significantly abnormal laboratory test result that the study doctor thinks needs medical follow-up, you will be notified by mail or phone, and asked to contact the research unit with your physician's name and phone/fax number. With your permission, the test results will be forwarded to your physician in order that s/he may give you medical advice as appropriate. Copies of the test results will not be given to you directly. If you do not have a physician, the study doctor will offer to help you locate one for follow-up care.

Urine Collection

Once during this study you must collect all your urine over a 24-hour period and keep it in a cooler until you bring it to the research unit. You will be provided with collection containers and a storage cooler.

Questionnaire

Once during this study you will complete a questionnaire that will ask for information on your smoking behaviors.

Cigarette Butt Collection

Once during this study you must collect and bring in to the research unit all cigarette butts from all the cigarettes that you smoked over a 24-hour period.

Topography Device

You must use a topography device with 4 of the cigarettes you smoke. This device will record information about how you smoke the cigarette. The study staff will show you how to use it. You may not keep the topography device, and must return it to the research unit.

***ABOUT BLOOD SAMPLES***

During this study, one blood sample will be taken from a vein in your arm. The total amount of blood being drawn in this study is about 2 tablespoons. For comparison, you give about 2 cups of blood at one time when you donate a unit at a blood collection center.

***COMPARISON OF YOUR CURRENT RESULTS TO YOUR PREVIOUS RESULTS***

Your results and responses in this study will be compared with your results and responses from the Covance Smoking Study to see what differences there are after changing cigarette brands.

**Risks of Being in This Study**

The risks of having blood drawn include bruising, infection, bleeding, and blood clot formation. Sometimes having blood drawn can sting and be uncomfortable. Some people faint when they have their blood drawn.

Cigarette smoking during pregnancy is associated with increased risk of spontaneous abortion, low birth weight infants, and perinatal mortality. Therefore, pregnant women cannot participate in this study and women of childbearing potential should avoid becoming pregnant during the study. Nicotine passes freely into breast milk and a nursing child may receive nicotine from a smoking mother's milk with the possibility of causing harmful side effects to the child. Therefore, women who are nursing cannot participate in this study. If you become pregnant during the study, you must notify the study doctor.

## Treatment for Injuries

Your safety is the major concern of every member of the staff. Please contact the study staff as soon as possible if you have injuries. The phone number for _____ is (  ) _____.

_____ will provide immediate medical treatment and follow-up care for injuries caused by being in this study. The costs for any other medical problems not caused by being in this study are your responsibility.

## If You Have Questions

Please contact the study doctor or the study staff with any questions you may have. They can be reached at _____.

For questions about your rights as a research volunteer, please contact the Institutional Review Board (IRB) office (608) 443-1415 or 1-888-220-7715. Letters may be sent to the attention of the IRB at 3402 Kinsman Blvd., Madison, WI 53704.

The Covance CRU IRB is the review board that approved this study. The IRB reviews each research study to make sure that the known risks to research volunteers are adequately presented in this consent form. The IRB also makes sure that this study meets federal regulations for human subject research. Approval by the IRB is necessary before a study can begin, but only you can decide if you wish to be in the study.

## Benefits of Being in This Study

This study will not improve your health or treat any medical problem you may have. If you have medical problems, you should see your own doctor about your care.

## Payment for Your Time

You will not be paid for the first visit to the research unit. If you complete all required study activities after the first visit, you will receive $____. A check will be mailed to you at the end of the study after you have completed all required study activities.

If you fail to return the topography device to the research unit, you will not be paid at all.

Smokers who decide to quit smoking during the study, but are otherwise able to continue in the study, will receive $____.

After you begin the study, if you are released, or if you choose to stop, you will only be paid for the time you spent in the study (at a lesser rate).

No taxes are deducted from your check. You are responsible for paying any state, federal, or Social Security taxes.

If you receive more than $600 in one calendar year from _____, you will receive a 1099 tax form the following January. _____ reports the money paid to you to the Internal Revenue Service.

## Costs to You

There are no costs to volunteers. The study Sponsor pays all the study costs.

## Protecting Your Privacy

As much as possible, your name and identity will be kept private. You will be identified by a unique number on many study records.

The people who are allowed to look at your study records include staff from Covance Clinical Research Unit Inc, independent study monitors contracted to work for Covance Clinical Research Unit Inc., and possibly governmental agencies as required by law. People from these organizations will be allowed to see and copy your study records. The study records will be checked to see that the study was conducted properly.

This study may be written about in medical or scientific journals, but your name or other identifying information will never be used in any public reports on this study.

The Sponsor, Philip Morris USA Inc., will only see the study data and results without your name on it. No identifying information will be given or shown to the Sponsor in any written, electronic or other form.

## Stopping the Study Early

The study Sponsor and/or the study doctor can stop the study at any time. You may also be required to stop being in the study if you do not follow the study directions, or do not meet the study requirements.

## Leaving the Study

Your decision to be in this study is completely voluntary. You may leave the study at any time. There are no penalties for leaving the study early. You will not lose any benefits for which you

qualify. You will be told about any new information about the study that might make you change your mind about being in this study.

## Volunteering to be in This Study

You may take as much time as you need to think about being in this study. Before you sign this form, please ask any questions you have about your part in this study or about the research. The staff will try to answer fully and clearly any questions you may have before, during and after this study. **You do not lose any of your legal rights by signing this form.** You will receive a signed copy of the Volunteer Information and Consent Form. You may request copies of your screening test results.

**Please read the following paragraph out loud to the person obtaining the consent.**

I have read the information in this study consent form. I have asked the staff any questions I have had at this time about my part in this study and about this research. I volunteer to take part in this study of my own free will. I consent to the use of my results and responses from the previous Covance Smoking Study for comparison with results in this study.

Your Signature Date/Time

**I have received a copy of this study consent form.**

**Your Signature** **Date**

**COVANCE STAFF ONLY**

Signature of Person Obtaining Consent and Verification of Literacy Date/Scientific Time



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